stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

§ 882.5900 Preformed craniosynostosis strip.

(a) *Identification.* A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

§ 882.5940 Electroconvulsive therapy device.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral ateriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.'' For availability of this guidance document, see § 882.1(e).

[69 FR 77900, Dec. 29, 2004]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards).

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification.* Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

[63 FR 40651, July 30, 1998]

§ 882.5975 Human dura mater.

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Human Dura Mater.'' See §882.1(e) for the availability of this guidance.

[68 FR 70436, Dec. 18, 2003]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Subpart B—Obstetrical and Gynecological Diagnostic Devices

Subpart C—Obstetrical and Gynecological Monitoring Devices

Subpart D—Obstetrical and Gynecological Prosthetic Devices

Subpart E—Obstetrical and Gynecological Surgical Devices

Subpart F—Obstetrical and Gynecological Therapeutic Devices